OFFICE OF SPECIAL MASTERS No. 00-331V September 21, 2005

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on June 6, 2000, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that MMR and acellular DPT vaccinations administered on June 16, 1997 caused Michael Cook (hereinafter, "Michael") twitching, light

¹ Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

sensitivity, and emotional fragility. Petition, at ¶ 4. This case was transferred to the undersigned on March 4, 2005.

The undersigned issued an unpublished decision on May 4, 2005, holding that Michael did not have a seizure after his MMR and DPaT vaccinations, but that, even if his twitching and head shaking were a seizure, it was afebrile and the vaccines did not cause it.

Petitioner appealed the decision in this case and the Honorable Marian Blank Horn remanded the case on June 23, 2005 for a hearing.

A hearing was held on September 9, 2005. Testifying for petitioner were petitioner, Lawrence Cook (petitioner's husband), and Dr. Carlo Tornatore. Testifying for respondent was Dr. Russell Snyder. During Dr. Snyder's testimony, respondent's counsel conceded that DPT more likely than not caused or significantly aggravated Michael's emotional and behavioral problems, but did not cause or aggravate his seizures or learning disabilities. The undersigned stated at the conclusion of the testimony that she would be ruling in favor of petitioner, having accepted the testimony of Dr. Tornatore that DPT caused in fact Michael to have an acute, non-Table encephalopathy, manifested by listlessness, a change in affect and behavior (weeping, temper tantrums) precipitated by a type of seizure known as cephalic or epileptic aura.

FACTS

Michael was born on January 20, 1992.

On August 27, 1992, he was brought to his doctor with a complaint that he was fussy and sleeping less but some. Med. recs. at Ex. 3, p. 2.

On August 20, 1992, Dr. Steven J. Schiff, a neurosurgeon, saw Michael to determine if he had craniosynostosis. Michael spent several months of his life in a baby seat and had developed

a flat occiput. X-rays suggested lamboid synostosis. On examination, Michael's head was brachycephalic with rather prominent parietal bosses. Dr. Schiff stated this appeared to be positional brachycephaly and not true craniosynostosis. Med. recs. at Ex. 3, p. 13.

On May 23, 1993, at the age of sixteen months, Michael was taken to the emergency department after having a seizure lasting approximately two minutes at 12:50 p.m. He was alert and responsive. Med. recs. at Ex. 8, p. 1. His temperature was 103.7°. Med. recs. at Ex. 8, p. 2. He had a positive strep A test. Med. recs. at Ex. 8, p. 4. He had gram positive cocci in pairs. Med. recs. at Ex. 8, p. 5. He was diagnosed with streptococcus pneumoniae. Med. recs. at Ex. 8, p. 6. A nurse next door to the Cooks had given Michael mouth to mouth four times. Med. recs. at Ex. 8, p. 9. He had a fever for three hours before he had the seizures. Med. recs. at Ex. 8, p. 17. Initially, he was a little lethargic, but on discharge from Fair Oaks Hospital, he was active and interested. *Id.* He was diagnosed with febrile seizure and strep throat. *Id.* See also med. recs. at Ex. 3, p. 4.

By May 24, 1993, Michael was back to his old self. Med. recs. at Ex. 3, p. 4.

On January 31, 1994, when Michael was two years old, Mrs. Cook stated that Michael had had a seizure at 5:30 a.m. in the context of a sore throat. He had a five-minute, febrile seizure during which his eyes rolled. It was tonic-clonic and occurred during sleep (he had been sleeping with his mother). He had 103.8° at the time, although 97.8° in the doctor's office. He was alert within 15-30 minutes after the seizure. *Id*.

On February 3, 1994, the doctor discussed Michael's two febrile seizures with Mrs. Cook. Michael's cousin had seizures. Mrs. Cook told the doctor that Michael had some intermittent shaking episodes during his first hour of sleep. Med. recs. at Ex. 3, p. 5.

On February 16, 1994, Michael had an EEG which was normal. He had isolated twitching movements in his sleep which Dr. Phillip L. Pearl stated were variably associated with myogenic (of muscular origin) artifact. There were no epileptiform features. Med. recs. at Ex. 3, p. 11.

On May 30, 1995, Mrs. Cook called her pediatrician to say that Michael had had stomach cramps for four days. Med. recs. at Ex. 15, p. 6. He saw the doctor that day. He had a history of pain with bowel movements since drinking a "Power Ranger" drink. He seemed to get gastrointestinal upset with milk products, too. Med. recs. at Ex. 15, p. 7. The doctor diagnosed him with gastroenteritis. *Id*.

On January 30, 1997, Mrs. Cook brought Michael in to Virginia Medical Associates for a referral because Michael snored and had respiratory distress. Michael was diagnosed with sleep apnea.² Med. recs. at Ex. 13, p. 5. Michael was referred to Dr. Zalzal.

On February 25, 1997, Dr. George H. Zalzal, an otolaryngologist, described Michael as a snorer and mouth-breather for many years. He was reported to stop breathing and gasp for air. He requested from Mrs. Cook the opportunity to assess the severity of Michael's apnea. Med. recs. at Ex. 13, p. 6; also Ex. 24, p. 18.

² Sleep apnea is "transient attacks of failure of automatic control of respiration, resulting in alveolar hypoventilation, which becomes more pronounced during sleep. It may result in acidosis and in vasoconstriction of pulmonary arterioles, producing pulmonary arterial hypertension." <u>Dorland's Illustrated Medical Dictionary</u>, 27th ed. (1988) at 112. "The cumulative effect of recurrent spells of apnea is hypoxemia and shallow, nonrefreshing sleep, which may lead to excessive drowsiness, personality change, impairment of intellectual functioning, and heightened tendency to accidents during waking hours." <u>Stedman's Medical Dictionary</u>, 27th ed. (2000) at 111-12.

On March 12, 1997, Dr. Zalzal noted that, by looking at an x-ray, he saw that Michael has prominent adenoid tissue in his nasopharynx, which could be the cause of his snoring. He was a candidate for an adenoidectomy with possible tonsillectomy. Med. recs. at Ex. 13, p. 7; also Ex. 24, p. 17. (There are no medical records filed showing that Michael had an adenoidectomy or tonsillectomy.)

On June 5, 1997, Michael saw his doctor with a low-grade fever and cough. His vaccinations were deferred. Med. recs. at Ex. 13, p. 8.

On June 16, 1997, at 1:45 p.m., when he was 5 ½ years old, Michael received MMR, acellular DPT, and oral polio vaccines. Med. recs. at Ex. 13, pp. 1, 9.

Four days later, on June 20, 1997, he saw his pediatrician at Pediatric Acute Care. The history Mrs. Cook gave was that, on the prior evening, June 19, 1997, Michael announced to his parents a vague sensation. Mrs. Cook stated Michael said he had "shaking in his head" that lasted about 15 seconds and occurred twice, once during dinner and once while playing with his father. He had no other complaints and nothing suggesting a postictal occurrence (i.e., after a seizure). He did not have any more episodes. At the doctor's office, there was no evidence of any problem. On examination of Michael's eyes's fundi (the part of the eye opposite the pupil), the doctor found him normal. His diagnosis was a habit tic. Med. recs. at Ex. 13, p. 10.

Two and one-half weeks later, on July 7, 1997, Mrs. Cook telephoned the pediatrician and said that Michael had an infection in his right molar and the dentist wanted to x-ray him and possibly give him penicillin. Mrs. Cook refused, stating that Michael had a shaking episode on June 5, 1997 and she was concerned about seizure activity. The nurse replying to Mrs. Cook's call told her it was safe to x-ray Michael and also safe for him to take penicillin. The nurse

consulted with Dr. Huang who stated she had never known an x-ray or penicillin to cause seizure activity. Med. recs. at Ex. 13, p. 11.

Ten days later, on July 17, 1997, Michael returned to Pediatric Acute Care, where Mrs. Cook told Dr. William Bekenstein that Michael was having episodes of crying very easily and was irritable. This was new behavior for him. She was concerned about his low blood sugar. Also, he was sensitive to light. Mrs. Cook noted that Michael got crying spells whenever he ate sugar. He did well if his mother eliminated sweets from his diet. Dr. Bekenstein diagnosed hypoglycemia.³ Med. recs. at Ex. 13, p. 12.

On July 22, 1997, Michael had his blood glucose tested. It was 77 mg/dl, which is on the low side of normal. Med. recs. at Ex. 13, p. 4.

Two and one-half months later, on October 7, 1997, Michael returned to Dr. Bekenstein because Mrs. Cook was concerned about Michael's hypoglycemia. She said Michael had an episode the prior week where he got the "shakes." Michael still described shaking in his abdomen and head, but Dr. Bekenstein noted there was no visible seizure activity. Med. recs. at Ex. 13, p. 14.

On October 13, 1997, Michael saw Dr. Kathleen M. Link, an endocrinologist, who thought his problems were not endocrine in nature and recommended a neurologic evaluation and a psychiatric evaluation. Med. recs. at Ex. 10, p. 1. Mrs. Cook told Dr. Link that when she

³ Hypoglycemia is "an abnormally diminished concentration of glucose in the blood, which may lead to tremulousness, cold sweat, piloerection [erection of the hair], hypothermia, and headache, accompanied by irritability, confusion, hallucinations, bizarre behavior, and ultimately, convulsions and coma." <u>Dorland's</u>, at 804. "Autonomic symptoms include sweating, trembling, feelings of warmth, anxiety, and nausea. Neuroglycopenic symptoms include feelings of dizziness, confusion, tiredness, difficulty speaking, headache and inability to concentrate." Stedman's, at 861.

switched Michael to a high protein diet in June, he seemed to do a little bit better until October 7, 1997, when he again had some major problems with tremors. Mrs. Cook described the tremors as waking him up and shaking inside his head and sometimes inside his stomach for the whole evening. She would give him protein which seemed to help and he would then go back to sleep. Otherwise, he was healthy and very bright, and got along with his peers. He did well in school. Med. recs. at Ex. 10, p. 19.

On October 17, 1997, Michael saw Dr. Gilbert August, a pediatric endocrinologist, at Virginia Medical Associates, concerning his hypoglycemia and questioned if he were having seizure activity. Med. recs. at Ex. 13, p. 15.

Two weeks later, on November 4, 1997, Michael saw Dr. Bennett Lavenstein, a pediatric neurologist. Mrs. Cook told Dr. Lavenstein that in mid-June, Michael received MMR, DPT, and OPV. Over the next two days, he was tired, listless, and moody with occasional crying. Dr. Lavenstein records, "He resolved from those symptoms and was unremarkable until July about two weeks later when he was noted to have some sensation of 'shaking in his head and shaking in his eyes' and would become tremulous." Med. recs. at Ex. 14, p. 1. At no time did Michael's parents notice that Michael had a tremor, but subsequently, on several occasions, Michael complained of "shaking in his stomach." *Id.* On occasion, Michael would develop features of tremulousness and tremor after eating various quantities of sugar. Michael's parents could not clearly define the amplitude and nature of his tremor. Since September, Michael had had intermittent tremulousness precipitated by a sugar load. He would also become tired and sleep more after ingesting large quantities of sugar. *Id.*

Michael's mother stated that, occasionally, Michael's eyes watered while he complained about shimmering and tremoring of his eyes. But neither parent saw any nystagmus (rapid, involuntary, oscillatory motion of the eyeball). Michael stated he could not tolerate heat or light as he once could. His gait, motor strength, coordination, and cognitive skills remained unchanged. A student in kindergarten, Michael was very bright, articulate, and socially interactive. *Id*.

As a very young child, Michael had two brief febrile seizures which were not associated with any sequelae. Otherwise, he had been in good health. *Id.* His family history is positive for epilepsy in a cousin. Med. recs. at Ex. 14, p. 2. One of his prior febrile seizures (at 18 months of age) was associated with a significant strep infection. *Id.*

On examination, Dr. Lavenstein found Michael to be neurologically normal. There was no evidence of any abnormality of movement and response. Dr. Lavenstein tested Michael for nystagmus with an opticokinetic drug and Michael's response was normal. With his arms outstretched, Michael did not have tremor. Michael touched his nose with his index finger, without any evidence of past pointing or distal tremor. Further testing showed no evidence of abnormality. Michael acted appropriately and was cooperative. *Id*.

Dr. Lavenstein concluded, "At this time Michael has had sensory symptomatology without overt objective visible symptomatology wherein he complains of these sensations of his eyes tremoring, his stomach shaking and feeling tremulous all over. With regard to his changes of behavior and his response to various sugar loads clearly I believe continuation of his pediatric endocrine work-up with glucose tolerance test, Insulin levels and other appropriate studies would be recommended." *Id.*

An EEG was done on November 14, 1997, which was normal in the prolonged 24-hour state. There was one report of restless movement, but no significant EEG change. Med. recs. at Ex. 14, p. 7; Ex. 10, p. 42.

An MRI performed on November 24, 1997 was normal. Med. recs. at Ex. 9, p. 11.

On December 10, 1997, Dr. Lavenstein saw Mrs. Cook and reviewed Michael's findings. Michael had low glucose at 43 mg/dl. Dr. Lavenstein stated, "At this time Michael's findings still by history are consistent with metabolic basis for his tremulousness based on his handling of glucose. I have asked at this point that the mother seriously pursue the work up with Dr. Link for evaluation of any hyperinsulin-like states or reactive hypoglycemia-like states or other causes of chronic hypoglycemia that may be responsible for his symptoms." Med. recs. at Ex. 14, p. 11. He suggested that Michael see a pediatric ophthalmologist about his undue photic sensitivity and increased tearing.

Dr. Lavenstein concludes, "At this time I emphatically told Mrs. Cook that there is no evidence of primary neurologic disease and that any further evaluation must really be carried from the endocrinologic standpoint." *Id*.

On December 29, 1997, Michael saw Dr. Link, the endocrinologist, again. He had a blood glucose of 43. His symptoms persisted as before with shaking inside and changes in behavior. He was now clingy in attachment to his mother. Once, very early in the morning, he was very weak and limp when he was staying with an uncle and had not eaten much the day before. When his mother appeared, he came around quickly and he was given food. He did not have a cold sweat, visible shakiness, or pallor. At this time, with a blood sugar of 43, Dr. Link recommended a thorough evaluation for hypoglycemia. Med. recs. at Ex. 10, p. 6; Ex. 9, p. 3.

Michael used to be cooperative in taking high protein snacks, but was now starting to refuse them and wanted sweet foods. His grandmother was dying and Mrs. Cook thought that might be affecting Michael. Med. recs. at Ex. 9, p. 3.

On December 31, 1997, Dr. Link's nurse Karen Kelley taught Mrs. Cook how to do home blood glucose monitoring on Michael. Mrs. Cook pricked him but could not get a full drop of blood and he refused to let her prick him again, although he said he would let her do it that night. Med. recs. at Ex. 9, p. 5.

On January 13, 1998, Michael saw Dr. Link again. Michael complained of shaking inside his head and would occasionally be limp in the morning if he missed dinner. He did respond to eating protein and even the shaking in his head sometimes responded to eating protein. Since he was last seen, Michael reported he no longer had the shaking in his head. He had one episode of being limp in the morning when he missed his dinner. *Id*.

In a letter dated January 20, 1998, Dr. Link states she saw Michael again and was still not convinced he had hypoglycemia. When he saw Dr. Lavenstein, Michael had a blood sugar of 41. She asked Mrs. Cook to start checking Michael's sugar at home when he had symptoms, but she did not do that. She did check Michael randomly and his sugars were always 81-90. Mrs. Cook gave the meter back to the pharmacy because she said that checking Michael's blood was very traumatic. Dr. Link told her it was very important to check during the time Michael was complaining of symptoms so as to determine whether low blood sugar played a part in this. Dr. Link thought Michael might have some medium chain CoA dehydrogenase deficiency which causes a failure of conversion from sugar metabolism to fat metabolism, which is not uncommon. Dr. Link noted that since she gave him the blood sugar testing equipment, Michael's symptoms

improved quite a bit although he still occasionally complained of stomach aches. He did not complain of shaking in his head any more. Med. recs. at Ex. 10, p. 7. Dr. Link discussed with Mrs. Cook further evaluation for hypoglycemia, including a glucose tolerance test and a 24-hour fast. Dr. Link was going to get Mrs. Cook a new meter so she could again test Michael at home should the symptoms occur to see if he is hypoglycemic during the symptoms. Med. recs. at Ex. 10, p. 8.

On April 29, 1998, Mrs. Cook telephoned her pediatrician. She was very upset because no one called her back. She stated that Michael has been having seizures and she wanted to know in what direction to go. Med. recs. at Ex. 13, p. 19. (There is no follow-up appointment filed in the records and no emergency room or hospital admission filed in the records to reflect that Michael had seizures in April 1998.)

Michael saw Dr. Lavenstein again on May 6, 1998. He planned to have Michael have a 24-hour EEG. Med. recs. at Ex. 10, p. 9.

On May 15, 1998, Dr. Val Abbassi, a pediatric endocrinologist, evaluated Michael for possible hypoglycemia. Mrs. Cook told Dr. Abbassi that, in April 1998, Michael had two seizures at night. Michael's neonatal period was complicated by respiratory difficulty and sleep apnea. He had two febrile seizures, one at 18 months during a bout of strep septicemia, and one at two years of age. In July 1997, he was put on a high protein diet to avoid the presumable hypoglycemic episodes. He currently ate three major meals and multiple snacks during the day. Michael's eyes were sensitive to light and he drank water excessively. Recently, he had trouble sleeping and twitched his muscles at night. His father had asthma since early childhood and his mother has chronic fatigue syndrome. Med. recs. at Ex. 10, p. 10. Michael's neurologic

examination was nonfocal. Dr. Abbassi's clinical impression was that his symptoms were compatible with either hypoglycemia or seizures. Med. recs. at Ex. 10, p. 11.

On June 5, 1998, Michael was taken to Fair Oaks Hospital emergency department with a seizure consisting of "full body tremors." Med. recs. at Ex. 8, p. 22. His temperature was 97.8°. His seizure occurred at 1:40 a.m. He had been sleeping when he started to tremble all over for 10 seconds. His mother easily woke him and then his trembling stopped. He felt fine then. Med. recs. at Ex. 8, p. 23.

On June 9, 1998, Michael had an EEG performed. The history was that Michael had a history of shakes. Mrs. Cook told Dr. Lavenstein that Michael had one seizure in April 1998 which wakened him from sleep with convulsions and another event one hour later. The EEG recorded frequent muscle movement artifact but no clear cut epileptiform disturbance. A number of jerks were recorded. When Michael emerged from sleep, the background recorded activity associated with the emergence of sleep without any paroxysmal epileptiform disturbance. On June 3, 1998, the EEG recorded paroxysmal spikes and slow wave discharges seen maximally frontally and bifrontally. Dr. Lavenstein's impression, signed June 9, 1998, was that Michael's 24-hour ambulatory Digitrace EEG was abnormal due to bifrontal hemispheric electrographic features of paroxysmal abnormality. Med. recs. at Ex. 10, pp. 12-13.

On June 10, 1998, Michael saw Dr. Lavenstein again. Michael had a 48-hour Digitrace EEG (see med. recs. at Ex. 14, pp. 19-20) which was normal during the first 24 hours, but in the second 24 hours, showed bifrontal epileptiform discharges without secondary generalization in his sleep recording. There was no correlation between the discharge and the subsequently noted findings (he had episodes during sleep of frequent muscle movement best described as

myoclonic⁴ movements). Michael had had a generalized seizure on June 5, 1998. Med. recs. at Ex. 14, p. 12.

Dr. Lavenstein said that Michael's sleep physiology might be due to apnea secondary to upper airway obstruction due to hypertrophied tonsils and adenoids. He recommended pursuing metabolic evaluation with Dr. Abbassi and also beginning Depakote for treatment of his primary EEG abnormality that correlated with his documented seizures. He also recommended a possible ENT evaluation of Michael's upper airway obstruction that may be associated with nocturnal apnea, producing decreased oxygen saturation and contributing to a hypoxic factor for a latent seizure disorder. In addition, Michael should be evaluated for any "glucose abnormalities that may have also been of concern in the past and have yet [to] be fully elucidated [as] a part of his ongoing investigation by pediatric endocrinology." *Id*.

On July 28, 1998, Michael returned to Fair Oaks Hospital for a sleep disorder study and polysomnogram report. Med. recs. at Ex. 8, p. 24. Mrs. Cook described Michael as experiencing constant twitching and jerking while asleep, where he moved his arms, hands, and shoulders, especially during the first few hours of sleep. Occasionally, she said he sat straight up in bed with all muscles extremely tight, but he was not awake at the time. Michael was tested overnight. He had mild periodic leg movements that on occasion were associated with an EEG arousal. His heart rate would increase to 120 beats per minute during the arousals. His EEG was unremarkable and revealed no evidence of seizure activity. Michael exhibited rare snoring and occasional mild loud breathing. Dr. Thomas J. LoRusso, board-certified in sleep medicine,

⁴ Myoclonus is "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." <u>Dorland's</u>, at 1090.

concluded there was no significant obstructive sleep apnea or hypopnea detected and no evidence of parasomnia or seizure activity. Med. recs. at Ex. 8, p. 24.

On August 13, 1998, Dr. Lavenstein saw Michael again after he had a sleep study. Med. recs. at Ex. 14, p. 18. He did not have obstructive apnea or hypoventilation. His EEG was unremarkable. He had mild rare snoring. Med. recs. at Ex. 14, p. 17.

On November 14, 1998, Dr. Abbassi wrote a follow-up note on Michael. Michael's fasting blood sugar of 79 mg/dl was normal. His fasting insulin was also normal. There was no evidence of hormonal or metabolic abnormalities. He considered hypoglycemia very unlikely. Med. recs. at Ex. 10, p. 18.

Dr. Lavenstein saw Michael on January 6, 1999. Michael was on Depakote. He had no focal findings. He had some diffuse joint pains and some neck pain, but no evidence of any other abnormality. His neurologic examination was normal. Mrs. Cook was concerned about his multiple rheumatologic complaints. Neurologically, Michael was doing quite well. Med. recs. at Ex. 7, p. 8; also Ex. 24, p. 13..

Dr. Lavenstein saw Michael on January 7, 2000, noting Michael had difficulties at school with space organization, problem solving, carrying over concepts, and retrieving and recalling information. He had features of a seizure disorder in the past, as reflected in an abnormal EEG. Med. recs. at Ex. 24, p. 12.

On January 3, 2001, Michael had an EEG which Dr. William M. McClintock viewed as mildly abnormal because of a single generalized bifrontal spike-and-wave discharge seen in drowsiness. Med. recs. at Ex. 24, p. 10.

Dr. Lavenstein saw Michael on January 12, 2001. His most recent EEG showed right frontal single sharp slow wave discharge, but was otherwise unremarkable. Med. recs. at Ex. 24, p. 9.

On May 23, 2001, Michael saw Dr. Ian H. Leibowitz, a gastroenterologist, for four episodes of abdominal pain and vomiting over five months. Mrs. Cook said that in each episode, Michael had fever to about 100°, with vomiting followed by diarrhea. These episodes occurred in February, March, and April. He had not had these episodes since April. Mrs. Cook felt that much of this might be anxiety-related because Michael got abdominal pain when he was nervous, mad, or upset. He had a history of intermittent abdominal discomfort for years. At age five to six, Michael had what he described as shaking in his stomach. Dr. Abbasi worked him up for hypoglycemia but made no findings. Mrs. Cook said that Michael had a seizure right after DPT vaccination and, since then, he had nocturnal seizures that Mrs. Cook felt were brought on by sugar. There are some anxiety problems and problems at school. His stool studies did not show infection. Med. recs. at Ex. 25, p. 3.

On October 4, 2001, Michael saw Dr. Peter Lee, another gastroenterologist, for evaluation of abdominal pain. He had a history of cyclical episodes of abdominal pain, nausea, low grade fever, and loose stools. Michael's symptoms were worse in the morning with episodes of regurgitation and abdominal grumbling. He normally had five stools per day, which were loose and yellow. His symptoms partially improved on Zantac. Med. recs. at Ex. 25, p. 5.

Dr. Lynn F. Duffy performed an esophagogastroduodenoscopy and biopsy on Michael on October 16, 2001. Her impression was mild esophagitis. Med. recs. at Ex. 25, p. 7. The surgical

pathology report, signed by Dr. Lucia Pastore, dated October 17, 2001, diagnoses reflux esophagitis. Med. recs. at Ex. 25, p. 6.

Dr. Lavenstein saw Michael on October 18, 2001, noting Michael had symptoms similar to attention-deficit disorder. In addition, Michael had a number of gastrointestinal symptoms, including diarrhea and abdominal pain, as well as intense anxiety. Med. recs. at Ex. 24, p. 5.

On November 2, 2001, Michael saw Dr. Leibowitz, the gastroenterologist. He was still having stomach aches although they were clearly better. They occurred usually in the morning and were better by 11:00 a.m. His stool was less frequent, occurring three times daily, without bleeding. His work up in the hospital was negative. Mrs. Cook wanted to do a food elimination diet, but was quite clear that she thought there was a frustration or anxiety component to this. Med. recs. at Ex. 25, p. 2.

On November 15, 2001, Dr. Burton H. Grodnitzky, a Ph.D. clinical psychologist, interviewed Michael followed by testing on December 4, 7, 21, and 27, 2001. Michael's neurologist, Dr. Lavenstein, referred Michael to this psychologist. Throughout the testing, there was no overt indication of seizure-like activity. Med. recs. at Ex. 18, p. 2. There were no overt indications of serious emotional problems. *Id.* He maintained satisfactory attention and was not overly restless. *Id.* Michael's IQ performance placed him in the high average range of intellectual functioning. *Id.* His attention/concentration level was normal. Med. recs. at Ex. 18, pp. 3-4. He performed well on perceptual-motor tests. Med. recs. at Ex. 18, p. 4. His written language score was one year below his chronological age. He had processing difficulties with phonemes. Med. recs. at Ex. 18, p. 5. His math skills were weak. Med. recs. at Ex. 18, p. 6.

Michael had much more difficulty expressing his thoughts in writing than verbally. Med. recs. at Ex. 18, p. 9.

On February 23, 2002, Michael saw his neurologist, Dr. Lavenstein, who noted that Michael had difficulties with memory, focus, linear concepts, frustration tolerance, and visual motor, although he functioned in the high-average range in verbal IQ and demonstrated an excellent ability to express himself. Michael's difficulties related to learning, written language, and mathematics. Med. recs. at Ex. 24, p. 2.

On November 23, 2002, Michael had an MRI done of his brain with special attention to the temporal lobes. Dr. Sam Cheng reported that Michael's MRI was normal. Med. recs. at Ex. 24, p. 25.

On December 13, 2002, Dr. David O. Clayton of the Child & Family Counseling Group, wrote a letter at Mrs. Cook's request, stating that Michael's anticipatory anxiety about having "spells" was too severe for him to return to school and he needed home-bound education. He saw Michael once for evaluation and spoke to his treating physicians. He diagnosed Michael as having anxiety disorder, learning disorder, seizure disorder, and moderate stressors. He intended to see Michael every week or two to address his anxiety. Med. recs. at Ex. 26, p. 1.

On December 18, 2002, Dr. Eric Steckler saw Michael who was referred for anxiety. He states that Michael's adverse reaction to immunizations at age 5 led to an "irritable spot on his frontal lobes," picked up by Dr. Lavenstein. Michael had two negative tests for attention-deficit disorder. Anxiety has led to bright red irritation at the esophageal junction, and diarrhea and vomiting. He had two episodes of high stress where he ran around banging furniture and talking gibberish for three hours. He lost feeling in his arms and had pressure in his chest. He did not

recognize his toys and was afraid of the clock pendulum. He had a normal EEG and CT scan that day. Going to school led to diarrhea and then these spells later. Michael had bad dreams of dead people raining on him. He is scared of escalators. His last episode was December 9, 2002 at home where he had been for several weeks. He said that someone was taking control of his body and his spirit was gone. He said his brain was taking control and was an enemy, that it had gone bad. Sometimes his brain went blank and he could not remember. Med. recs. at Ex. 26, p. 2.

Dr. Steckler diagnosed generalized anxiety disorder, mixed receptive-expressive language disorder, seizure history, esophagitis, and problems with his primary support group. Med. recs. at Ex. 26, p. 3.

On January 2, 2003, Michael saw Dr. Steckler again. Mrs. Cook reported that Michael had a good holiday, but it was when he got frustrated in school that "the irritation in his frontal lobe acts up." Michael's home school was to begin the following week. When Michael returned to school the prior year, he was highly frustrated, but did not have episodes. Now he was 10 years old and would begin sixth grade next year in a new building. Mrs. Cook was concerned that Michael would lose his mind and never come back. He has anxiety over assignments.

Michael said he was not nervous about homebound school because he knew the tutor and, if he needed to stop at home, he could stop, but at school, he could not take a break and felt overwhelmed because he wanted to do well. His handwriting was messy and he had writer's cramp. He was sleeping better, but still nervous about little things, involving not being able to reach friends at home. Dr. Steckler noted Michael had anxiety and/or psychosis. Med. recs. at Ex. 26, p. 4.

On January 17, 2003, Michael returned to Dr. Steckler. Michael did well with his first week of home school. He had some gastrointestinal stress, nausea, and vomiting. Med. recs. at Ex. 26, p. 5. On the same date, in a later session, Michael said he was nervous before the tutor and was starting to toss and turn at night again. Med. recs. at Ex. 26, p. 6.

On March 20, 2003, Dr. Rajesh Mehra, D.O., notes that Michael's psychiatrist ordered an electrocardiogram (EKG) for Michael because of his tachycardia. Michael was on the anti-depressant Pamelor. Med. recs. at Ex. 27, p. 4. Michael's EKG was normal. Med. recs. at Ex. 27, p. 9.

In Michael's eighth session with Dr. Steckler on September 17, 2003, Dr. Steckler comments that the family moved to Leesburg where there was a great support system. Med. recs. at Ex. 26, p. 10.

On February 25, 2004, Dr. Lee, the gastroenterologist, wrote a letter stating that Michael has chronic abdominal pain which strenuous physical activity aggravated, resulting in severe abdominal pain and cramping. He recommended that Michael be excused from a one-mile race because of his chronic medical issues. Med. recs. at Ex. 24, p. 1.

On May 24, 2004, Michael went to Children's National Medical Center in an anxiety state. Med. recs. at Ex. 24, p. 19.

On that same date, Dr. Lavenstein wrote Dr. Mehra that Michael was doing beautifully. He was seizure-free and, in the past, had normal EEG and MRI. His regimen of clorazepate and Pamelor was to manage his anxiety. His neurological examination on May 24, 2004 was unremarkable and within normal limits. Med. recs. at Ex. 27, p. 8.

On August 10, 2005, Dr. Lavenstein wrote a summary letter of his experience treating Michael as his pediatric neurologist. Dr. Lavenstein states that Mrs. Cook reported that, two days after Michael received MMR, DTP, and oral polio vaccines, Michael was somewhat tired, listless, moody, and occasionally cried. Those symptoms resolved and he was unremarkable until about two weeks later, when he had head and eye shaking and was tremulous. He was tremulous and had tremor after eating various quantities of sugar. Dr. Lavenstein saw him in November 1997, at which time Mr. and Mrs. Cook told him that, since September 1997, Michael had intermittent tremulousness, fatigue, and increased sleeping, all of which a large sugar load precipitated. Michael did not have focal neurologic change in motor strength, gait, coordination, or cognitive skills. In November 1997, Michael was in kindergarten and was described as bright, articulate, and socially interactive. He had two febrile seizures when he was a very young infant without sequelae and was generally in good health. He has a cousin with epilepsy. Med. recs. at Ex. 28, p. 1.

In 1997, Michael had sensory symptomatology without overt objective findings. These symptoms were not associated with any change in mental status. An EEG done in 2001 was mildly abnormal because of a single generalized bifrontal spike wave discharge seen in drowsiness for which Depakene was used. He was on Depakene and chlorazepate and remained seizure free through May 2004 with normal MRI and normal EEGs after the abnormal EEG in 2001. His neurological examination remained intact. Med. recs. at Ex. 28, p. 2.

In summary, Dr. Lavenstein states that Michael was followed neurologically for a seizure disorder, has done well, and has had no sequelae of the seizure disorder. His neurological examination remained intact. Dr. Lavenstein has not seen Michael since May 2004. *Id.*

Other Submitted Material

Respondent filed Tab 2 to Dr. Snyder's expert report which is Exhibit A for respondent. Tab 2 is chapter 18, "Epileptic Auras," by N.K. So from a textbook, The Treatment of Epilepsy. Principles and Practice, 3d ed., ed. E. Wyllie (2001) at 299-308. Dr. So describes "aura" as reports of altered sensations. These sensations include "dizziness, warmth, cold, generalized tingling, anxiety, and a 'spaced-out' or confused feeling. Rarely, ill-formed visual imagery and abdominal sensations have been reported." *Id.* at 299. An aura reflects "activation of functional cortex by a circumscribed seizure discharge...." *Id.* "Multiple sensations can occur even when seizure activity is relatively confined to one region, as at the start of temporal lobe seizures." *Id.* at 300. "An aura provides evidence of focal seizure onset." *Id.* at 301. "Cephalic aura includes ill-defined sensations felt within the head, such as dizziness, electrical shock, tingling, fullness, or pressure." *Id.* at 305. "[C]ephalic sensations have been reported as auras in focal seizures arising from all brain regions...." *Id.* Under the category of emotional auras, Dr. So describes fear as ranging "from mild anxiety to intense terror...." *Id.* Other patients "localize the sensation to the chest or stomach...." *Id.*

Petitioner filed Exs. 29 and 30 at the hearing from a textbook by Dr. John Menkes. They contain a discussion of the symptoms of partial complex seizures, including auras and temper tantrums as well as perceptual disturbance.

TESTIMONY

Petitioner testified first. She described Michael before his vaccinations in his fifth year of life as very bright, happy, and highly intelligent. He was always in a good mood and had a lot of friends. He had such a good sense of humor that he could make adults laugh.

On June 16, 1997, at 1:45 p.m., Michael received acellular DPT, MMR, and oral polio vaccines. His appetite at dinner was a little off. What struck petitioner most was that Michael's personality changed in front of her eyes. He was not the same child. On the evening of June 19, 1997, he complained that he had shaking in his head and behind his eyes. He did not have fever. He was not happy and was crying all the time. He was lethargic and just lay around. He was frustrated and had temper tantrums. He said he did not feel good.

Petitioner called the pediatrician on June 17, 1997 and spoke to a nurse. Michael got frustrated and threw things. She saw Dr. Bekenstein, Michael's pediatrician, on June 20, 1997, at 4:30 p.m. and told him that, the evening before, he had played with his father. But the behavior continued and his unhappiness never went away.

By July 17, 1997, Michael was crying very easily. After the vaccinations, he would not go out in the sunlight. He complained that his eyes were hurting within 48 hours of vaccination. His photosensitivity lasted all summer. His ears hurt him when he heard loud noises. He complained it was too hot for him to go outside.

In April 1998, petitioner saw Michael have visible seizures with tremors, eyes rolled and, later in the afternoon, body stiffening and uncontrollable shaking.

Lawrence Cook, Michael's father, testified next. He said that Michael was a very amusing little boy at a young age. On June 16, 1997, he got home from work between 6:00 and 7:00 p.m. He noticed a marked difference in Michael's personality when he played with him. Michael would go along with the play but he was not himself. He was more detached and distracted. They read together or played catch, but Michael was sad, anxious, cranky, and unfocused mentally, which Mr. Cook noticed between June 16 and 17, 1997.

Michael would tell Mr. Cook that his eyes were shaking on the inside. From June 16, 1997 until today, Michael had a total change and a downhill slide in personality, demeanor, and physiology. Michael is now 13 years old and, when his father asked him where his sense of humor had gone, Michael responded that he lost it.

Michael also had problems with digestion, sleeping, anxiety, and energy after the vaccinations in question.

Dr. Carlo Tornatore, a neurologist, testified next for petitioner. His opinion is that Michael's complaint of shaking in his head and behind his eyes in the days after his acellular DPT vaccination indicate he had an aura, which represents electrical activity in the brain.

Michael's aura was cephalic. A Digitrace EEG showed spiking in the frontal lobes. On June 3, 1998, Michael had a paroxysmal spike and slow wave discharge in his frontal lobes bilaterally. The EEG findings support a diagnosis of epilepsy. Although earlier EEGs were normal, an EEG may not detect a seizure focus.

Dr. Tornatore noted Michael's fairly significant change in his medical condition after vaccination. He had a change in affect and behavior, i.e., he was listless immediately post-vaccination and complained of shaking in his head and behind his eyes. He was diagnosed subsequently with a seizure disorder. Dr. Lavenstein, Michael's pediatric neurologist, mentioned in his records ruling out partial complex seizures with aura in the absence of objective tonic/clonic activity. An aura heralds focal seizure onset. A seizure focus can cause different seizures at different times.

Dr. Tornatore's opinion is that Michael had an acute encephalopathy post-vaccination as manifested by listlessness, change in affect and mood (temper, tearfulness) and cephalic aura

(feeling he had shaking in his head and behind his eyes). The vaccine injured his frontal lobe, leading to a change in his behavior. The frontal lobe is the seat of our emotions. Aura is a focal, epileptic seizure. Sequelae of Michael's vaccine injury are his psychiatric problems, anxiety, and learning disabilities. This is a non-Table encephalopathy.

Michael had a propensity for seizures since he was an infant and toddler, having had two febrile seizures at those times.

Dr. Tornatore explained how acellular DPT caused Michael's reaction. Acellular DPT still contains endotoxins, although in a smaller amount than whole cell DPT. These endotoxins can irritate or injure the brain and cause seizures as part of an acute encephalopathy. Some of Michael's gastrointestinal symptoms can be an aura as well since epigastric and visceral symptoms can compose aura.

Dr. Tornatore stated that Michael still has an injury to his frontal lobes which affects his emotional and cognitive status. Michael now has chronic encephalopathy.

Dr. Russell B. Snyder, a pediatric neurologist, testified for respondent. He testified that Michael has partial seizures and may have frontal lobe epilepsy. There is a higher incidence of behavior problems and learning disabilities among epileptics.

Dr. Snyder agreed that Michael's behavior changes were due to the vaccinations. Not feeling well is common after DPT. His reaction to the vaccination involved behavioral components. Michael had a unique response to DPT. This is not something seen in the course of things. Dr. Snyder stated Michael had an adverse emotional response to the vaccine. DPT led to Michael's listlessness, irritability, lethargy (not wanting to play, not feeling well, insomnia,

anger), and his emotional problems. Dr. Snyder admitted that Michael has a chronic encephalopathy, i.e., chronic brain injury.

Respondent's counsel stated that respondent conceded that DPT more likely than not caused or significantly aggravated Michael's emotional and behavior problems, but did not concede that there was any causal relationship to Michael's seizures or learning disability.

The undersigned ruled from the bench that Michael had an acute, non-Table encephalopathy (based on his change in personality, aura, lethargy) which included seizures that began as aura and were ultimately diagnosed as frontal lobe, and that DPT caused in fact Michael's acute, non-Table encephalopathy based on the effect of DPT's endotoxins on Michael's brain. Moreover, the sequelae of his acute, non-Table encephalopathy are his psychiatric problems, anxiety, and learning disabilities.

DISCUSSION

Petitioner does not allege a Table injury. Dr. Tornatore opined that acellular DPT caused in fact a non-Table acute encephalopathy. Therefore, petitioner must prove her allegations by causation in fact. To satisfy her burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Althen v. Secretary, HHS, ____ F. 3d _____, 2005 WL 1793399 (Fed. Cir. 2005); Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." <u>Grant, supra, 956 F.2d at 1149</u>. Mere temporal association is not sufficient to prove causation in fact. <u>Hasler v. US, 718 F.2d 202, 205</u> (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the vaccine, Michael would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

We are not dealing here with someone who has an isolated, afebrile seizure after receiving DPT without any other symptoms, much less encephalopathic symptoms. In such a case, the undersigned has consistently ruled that DPT did not cause the afebrile seizure.⁵

We are here dealing with the allegation of an acute, non-Table encephalopathy, one of whose symptoms is a type of seizure called aura. The undersigned has ruled in other cases that, where a petitioner proves other symptoms in addition to a seizure that would constitute encephalopathic symptoms, petitioner may prevail in a vaccine case.

⁵ See Nanez v. Secretary of HHS, No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003); Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, *11 (Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, supra; Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The Institute of Medicine (IOM) also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.

In a death case, Misenko v. Secretary, HHS, No. 92-0013V, 1995 WL 7641436, at *14-15 (Fed. Cl. Spec. Mstr. 1995), the undersigned "held that post-DPT symptoms of extreme irritability, anorexia, and insomnia, followed by lethargy and death, are evidence of a Table encephalopathy (before the regulation change) causing death in a vaccinee." Cited in Clements v. Secretary, HHS, No. 95-484V, 1998 WL 481881, at *13 (Fed. Cl. Spec. Mstr. 1998) (petitioner did not prevail where the only symptomatology post-DPT was a seizure). Once the regulation changing the aids to interpretation of a Table acute encephalopathy occurred in 1995, fewer cases could be resolved in favor of petitioners under the category of Table acute encephalopathy.

⁶ 60 Fed. Reg. 26:7694 (Feb. 8, 1995), section 100.3(b) Qualifications and aids to interpretation. (2) Encephalopathy. For purposes of paragraph (a) [the Vaccine Injury Table] of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination. (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization. (B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following: (1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis; (2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and (3) A seizure associated with loss of consciousness. (D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater ...: (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

In a discussion of causation-in-fact encephalopathy in the tuberous sclerosis⁷ ("TS") cases, the undersigned ruled that, unless a petitioner had an acute, non-Table encephalopathy, manifested by symptoms such as crying, anorexia, insomnia, fever, moodiness, irritability, depression, "or [the child] behaves in any other abnormal way that would lead a parent as well as a physician to assume the child was unwell," the undersigned would hold that TS and not DPT caused the seizure. The undersigned also held that a child need not manifest all these symptoms to manifest an acute, non-Table encephalopathy, but "where a TS child received DPT vaccine and remain[ed] perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure." Barnes v. Secretary, HHS, 1997 WL 620115, at *32, *33 (Fed. Cl. Spec. Mstr. 1997), aff'd sub nom. Hanlon v. Secretary, HHS, 40 Fed. Cl. 625 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999), cert. denied sub nom. Hanlon v. Shalala, 530 U.S. 1210 (2000). TS was known to cause seizures. 1997 WL 620115, at *32.

In this case, unlike cases in which a DPT vaccinee has an afebrile seizure but no acute encephalopathy, petitioner prevails because she has successfully proved that Michael's abrupt change in personality from happy and amusing to tearful, frustrated, angry, plus his listlessness, not feeling good and symptoms of aura (the sensation of shaking in his head and behind his eyes), constitutes an acute, non-Table encephalopathy. The cause of this encephalopathy is the

⁷ "Tuberous sclerosis-also called tuberous sclerosis complex (TSC)1 - is a rare, multi-system genetic disease that causes benign tumors to grow in the brain and on other vital organs such as the kidneys, heart, eyes, lungs, and skin. It commonly affects the central nervous system and results in a combination of symptoms including seizures, developmental delay, behavioral problems, skin abnormalities, and kidney disease." http://www.ninds.nih.gov/disorders/tuberous sclerosis/detail tuberous sclerosis.htm#41993220

effect of endotoxins in acellular DPT acting upon the frontal lobes of Michael's brain, creating aura which manifested as his bizarre behavior, and ultimately clinical seizures, and also affected his gastrointestinal system, leading to the sequelae of psychiatric problems and learning disabilities.

Michael's symptoms were consistent from just a few days after vaccination, when he had his personality change and complained of shaking. One month after DPT, according to the medical records and petitioner's testimony, Michael still had emotional lability, photophobia, and irritability. Almost four months after the vaccinations at issue, Michael returned to his pediatrician, having had an episode of shakes the prior week. He still described shaking in his head and abdomen. Almost five months after the vaccinations at issue, Michael saw the pediatric neurologist, Dr. Bennett Lavenstein, and Michael still complained of tremor.

Mrs. Cook gave a history to Dr. Abbassi and Dr. Lavenstein of Michael's having two brief seizures in April 1998. Mrs. Cook took Michael to an emergency room on June 5, 1998 and gave a history that he had full body tremors at 1:40 a.m.

On June 9, 1998, Dr. Lavenstein signed a report describing Michael's first abnormal EEG: bifrontal hemispheric electrographic features of paroxysmal abnormality. At this point, Dr. Lavenstein put Michael on an anti-convulsive.

Petitioner has presented a credible case that DPaT caused Michael's acute, non-Table encephalopathy, composed of aura, listlessness, and psychological disturbances (anxiety, weeping, etc.), leading to the sequelae of clinical seizures, psychiatric problems, and learning disabilities. Respondent has partially conceded liability in this case: that DPaT caused Michael's emotional difficulties. The court holds that Dr. Tornatore's explanation of the effect of DPT

vaccine in creating aura (shaking in his head, behind his eyes, and ultimately in his stomach), patent seizures (in 1998), psychiatric problems, and learning disabilities is credible and manifests a logical sequence of cause and effect.

CONCLUSION

Petitioner is entitled to reasonable compensation. If the Honorable Marian Blank Horn directs the undersigned to proceed with damages, the parties may proceed with a telephonic status conference soon to discuss the filing of life care plans, unless the parties agree on a joint life care plan. Alternative dispute resolution is also available. If an amicable settlement is not forthcoming, the undersigned will hold a damages hearing if Judge Horn directs the undersigned to do so.

IT IS SO ORDERED.	
DATE	Laura D. Millman
	Special Master